

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF PUERTO RICO

UNITED STATES OF AMERICA,

Plaintiff,

v.

CARLOS ORREGO-MARTINEZ,

Defendant.

CRIM. NO. 02-465 (DRD)

ORDER ON MOTION FOR NEW TRIAL

As ordered by the Court of Appeals in its Judgment of June 20, 2007, received in June 21, 2007, the court proceeds to entertain on the merits defendant's request for relief of judgment under Fed.R.Crim.P. 33.

STANDARD UNDER FEDERAL RULE CRIMINAL PROCEDURE 33

Fed.R.Crim.P. 33 provides two jurisdictional bases for a new trial motion. "Rule 33 provides seven days in which a motion for new trial may be filed unless there is newly discovered evidence." United States v. Lema, 909 F.2d 561, 565 (1st Cir. 1990). "[A]ny order extending the time to file a motion for new trial must be issued within the seven-day period." United States v. Wiman, 77 F.3d 981, 987 (7th Cir. 1995). A motion for new trial grounded on newly discovered evidence may be filed any time within three (3) years after the verdict or finding of guilty, and may be granted by the district court "if the interest of justice so requires." Fed.R.Crim.P. 33 (1999). The statute of limitations for a Rule 33 based upon newly discovered evidence begins to run on the day the verdict or finding of guilty is rendered. J. Moore, 26 Moore's Federal Practice § 633.23[1] (3rd Ed. 1997). "[N]ewly discovered evidence must be

material to the issues involved [at trial]” United States v. Hanoum, 33 F.3d 1128, 1130 (9th Cir. 1994)(citation and quotations omitted). In addition, the “‘newly discovered evidence’ is limited to where the newly discovered evidence relates to the elements of the crime charged.” United States v. Mett, 65 F.3d 1531 (9th Cir. 1995)(quoting Hanoum, 33 F.3d at 1130).

Further, “ [n]ew trials may be granted on several grounds, including inter alia newly discovered evidence, juror bias, prosecutorial misconduct, ineffective assistance of counsel, witness perjury, or simply that the verdict was against the great weight of the evidence.” United States v. Arena, 918 F. Supp. 561, 566 (N.D.N.Y. 1996). However, as stated in United States v. Leach, 427 F.2d 1107, 1111 (1st Cir. 1970),

Motions for a new trial are directed to the trial court’s discretion. Under its broad power, the court may weigh the evidence and consider the credibility of the witnesses. The remedy is sparingly used, the courts usually couching their decisions in terms of exceptional cases, . . . miscarriage of justice, . . . and where the evidence preponderates heavily against the verdict.

A four-part test is used to evaluate a request for a new trial on the basis of newly discovered evidence. “The defendant bears the weighty burden “to establish that ‘the evidence was: (I) unknown or unavailable at the time of trial, (ii) despite due diligence, (iii) material, and (iv) likely to result in an acquittal upon retrial.’ ” *Id.* (quoting United States v. Montilla-Rivera, 115 F.3d 1060, 1064-65 (1st Cir.1997)).

The court merely has restated the general standards of Fed.R.Crim.P. 33 and unquestionably obeys the mandate of the Judgment of June 20, 2007 based on the case of United States v. Graciani, 61 F.3d 70, 77 (1st Cir. 1995). (“Concededly, a motion for a new trial based on newly discovered evidence can be brought while a criminal case is pending in direct appeal.” The case was remanded by the Court of Appeals for the Rule 33 motion to be entertained by the

trial level court.

ARGUMENTS BY DEFENDANT

I. The defendant argues that the government changed its theory of the crime during trial relating to the offenses charged in the indictment. (Orrego's Mot., Docket 207 pp. 5-12) Defendant claims that the Government charged the defendant with defrauding and misleading only the United States Customs Service and that the Government changed its theory of the case to include the FDA and "end users" (the costumers at the beauty salons) as other parties defrauded.

This claim assumes certain facts that are not correct. First, the claim presumes that the Government charged the defendant in the indictment of solely defrauding and misleading U.S. Customs. Notwithstanding, the indictment in this case does not specifically identify the defrauded party. Moreover, the law does not require the identification of any defrauded party in a case involving the introduction of adulterated devices in violation of the Federal Food, Drug and Cosmetic Act. As established in U.S. v. Arlen, 947 F.2d 139, 145 (5th Cir.1991), ("[t]he prosecution must prove beyond a reasonable doubt that defendant intended to defraud or mislead someone, but the indictment need not specify the intended victim; the focus is on defendant's intent, not the victim's identity.")¹ The evidence at trial showed that the defendant intended to

¹ The Arlen court expanded on the basis of its decision, as follows:

"[T]he statute does not specify *who* must be defrauded or misled to trigger the felony provisions of § 333(b). The district court held that the government could satisfy this requirement of § 333(b) by establishing that Arlen had the intent to defraud or mislead a government regulatory agency. Arlen argues that this interpretation is incorrect because the felony provisions of 333(b) are triggered only if a defendant defrauds or misleads his purchaser.

Although we have not previously decided this question, three other circuits have, and all three have agreed with the government's position here. See United States v. Bradshaw, 840 F.2d 871(11 Cir.), *cert. denied*,

defraud not only U.S. Customs, as when he himself carried the imported products, (as compared when he caused to import the product through international air carrier), but the F.D.A. and the clients of the beauty salons: the victims injected with the substances. Moreover, since the matter at issue fails to constitute “newly discovered evidence,” but constitutes a pure question of law the defendant is barred from presenting the same through a Fed.R.Crim.P. 33 as the same is well beyond seven (7) days of his guilty verdict.

II. The defendant argues that “the product which the Government seized at the Salon was ‘Silicex’ from Venezuela when in fact, the product was ‘Biopolymer’ which emanated from Miami, Florida.” Defendant further argued that the product did not come from Dominican Republic. (Orrego Mot.: pp. 5, 8, 9).

This argument by defendant is meritless as the determination of guilt was grounded on introduction of an adulterated device (liquid injectable silicone and *Karthy Swed*) for Counts [Three](#), Four, Five, Six and Seven. The evidence to establish each of the elements of the

488 U.S. 924, 109 S.Ct. 305, 102 L.Ed.2d 324 (1988); United States v. Mitcheltree, 940 1329 (10th Cir.1991); United States v. Cambra, 933 F.2d 752 (9th Cir.1991).”

... ..

The government’s interpretation of § 333(b) is consistent with the structure of the statute. As previously discussed, section 333(a) provides that anyone who violates a provision of § 331 commits a misdemeanor. Section 333(b) provides that anyone who does so with “intent to defraud or mislead” commits a felony. Several of the twenty acts § 331 proscribes concern only the government. See 21 U.S.C. § 331(e) (failure to permit FDA access to records and failure to make reports to FDA); § 331(f) (refusal to permit FDA inspection); § 331(p) (failure to register with the FDA). As the Bradshaw court noted, “[a]fter reading these sections with § 333, it is clear that the FDA is the entity most likely to be defrauded under these provisions.” Bradshaw, 840 F.2d at 874. Arlen’s interpretation of § 333(b), that the government cannot be a defrauded or misled victim, would lead to the conclusion that there could never be a felonious violation of §§ 331(e), (f), or (p). Such a result would be contrary to the plain inclusive language of § 333(b), which contemplates both misdemeanor and felony violations for all § 331 offenses.”

Arlen, 947 F.2d at 142.

importation of the devices is summarized in the table below:

COUNT	Substantive offense conduct	Evidence introduced at trial
THREE	Introduction of liquid injectable silicone on or about July 3, 2001, from Venezuela.	DHL airway bill and shipping documents, parcel number 6651864472 and receipt issued by the sender, <i>Belleza Integral</i> in Venezuela, to Carlos Orrego, in Miami, Florida. (Govt. Exh. 32). <i>Belleza Integral</i> invoice shows sale and shipment of <i>Silicex</i> , among other products.
FOUR	Introduction of liquid injectable silicone on or about August 1, 2001, from Venezuela	DHL airway bill and shipping documents, parcel number 6651864565 and receipt issued by the sender, <i>Belleza Integral</i> in Venezuela, to Carlos Orrego, contact person, at Evelyn Valentín's Salon in Puerto Rico. (Govt. Exh. 33). <i>Belleza Integral</i> invoice shows sale and shipment of <i>Silicex</i> , among other products.
FIVE	Introduction of liquid injectable silicone on or about February 19, 2002, from the Dominican Republic.	Testimony of María Polanco, beauty salon owner. Testified that defendant injected persons at her salon with biopolymer (<i>biopolímero</i> , in Spanish) (T.T. October 7, 2003, p. 36-38). Orrego's passport (Gov. Exh. 3) bears a stamp showing an exit from the Dominican Republic on February 19, 2002. Orrego's client list at Polanco's salon for February 19, 2002 (Gov. Exh. 59), shows clients set for retouching (<i>retoque</i>), evaluation, and injecting with the biopolymer. Polanco testified that Orrego would bring the substances he injected to the salon and would take them with him (T.T. October 7, 2003, p. 49).
SIX	Introduction of liquid injectable silicone on or about March 18, 2002, from the Dominican Republic.	Orrego's passport (Govt. Exh. 3) shows him departing the Dominican Republic on March 18, 2002. Esthetics International evaluation sheets (Govt. Exh. 7) show that Orrego worked at Evelyn Valentín's salon on March 19, 2002. Two vials (Govt. Exh. 18 and 19) and two syringes (Govt. Exh. 16 and 17) containing liquid injectable silicone, were seized at Evelyn Valentín's salon during the execution of a federal search warrant on March 20, 2002, the date was arrested.

COUNT	Substantive offense conduct	Evidence introduced at trial
SEVEN	Introduction of <i>Karthy Swed</i> on or about March 18, 2002, from the Dominican Republic.	Orrego's passport (Govt. Exh. 3) shows him departing the Dominican Republic on March 18, 2002. Esthetics International evaluation sheets (Govt. Exh. 7) show that Orrego worked at Evelyn Valentín's salon on March 19, 2002. Two vials of <i>Karthy Swed</i> (Govt. Exhibits 24 and 25), were seized at Evelyn Valentín's salon during the execution of a federal search warrant and arrest of Orrego at the salon on March 20, 2002.

The court further briefly explains the evidence to warrant the verdict.

On February 20, 2002, agents from the FDA performed a trash recovery of Evelyn Valentín's Salon. From the trash, agents obtained syringes and various bottles related to the treatments. (T.T.: 10/10/03: pp. 20-22, 29). On March 20, 2002, Orrego, together with Sergio Lopez and Evelyn Valentín were arrested at the salon by FDA agents. The agents seized the products being used by Orrego to inject the clients at the beauty salon. Evidence was later produced as to the products used on customers at each salon where services were provided (see discussion *infra*). (T.T.: 10/10/03: p. 32). The day prior to the both the trash recovery and his arrest, Orrego had entered Puerto Rico from the Dominican Republic. Orrego's passport showed the entry stamps and his personal agenda showed the salons visited. (T.T.: 10/10/03: pp. 23, 33).

Orrego was the person in charge of injecting all the clients and also purchasing the implants and drugs associated with the use of injection implants into human beings (usually under facial skin but other times including other parts of the body). (T.T.: 10/02/03: pp. 82, 98-99).

On July 3, 2001 and August 1, 2001, Orrego purchased biopolymers, known as "Silicex", from a business known as *Belleza Integral* in Venezuela, who would send the implants to him by

way of DHL international mail carrier. (T.T.: 10/1/03: pp. 116, 133-135; 10/3/03: p. 28; 10/6/03: pp. 20-22). Orrego also purchased Karthy Swed from Bioserum Laboratories in Guatemala. Both of these products did not have the required approval by FDA for injection for authorized cosmetic purposes. These adulterated devices are the object of counts Three, Four, Five, Six and Seven. See discussion *infra*.

Whenever Orrego came to Puerto Rico to inject persons at Evelyn Valentin's Salon, he would sometimes transport the implants with him in a small black colored bag. (T.T.: 10/2/03: pp. 74-75; 10/01/03: p. 25; 10/02/03: pp. 103-104). He was traveling either from the Dominican Republic or Miami. (See discussion *infra* Part VII). He would not leave the substances at the salon but always took them with him when he left. (T.T.: 10/1/03: pp. 24-25; 10/7/03: p. 92). He was the person solely responsible for injecting the implants into human beings and was responsible for purchasing and transporting the unlawful products into Puerto Rico. The fact that co-defendant Sergio López did not know the specific products used, as alleged by Orrego, is immaterial since this part of the conspiratorial conduct had been delegated to Orrego. Further, the evidence reveals that the specific person that had the technical knowledge as to the substances used and to be injected into individuals was Orrego. Orrego admitted in his testimony that he received fifty percent (50%) of the profits of Esthetics International, (a corporation used by López and Orrego), in part because he had to purchase the biopolymers and arrange for their transportation. (T.T. October 15, 2002, p. 127-128). Co-conspirators are not, pursuant to law, required to know what other co-conspirators are doing within the conspiracy since "the defendant need not have knowledge of every detail or phase of a conspiracy and the defendant's connection therewith is sufficient to convict. . ." United States v. McCarthy, 611 F.2d 220, 221 (8th Cir.

1979) citing Blumenthal v. United States, 332 U.S. 539, 557 (1947). Further “. . .so long as the partnership in crime continues, the partners act for each other in carrying it forward . . . an overt act of one partner may be the act of all without any new agreement specifically directed to that act ...” Pinkerton v. United States, 328 U.S. 640, 642-646 (1946). (T.T.: 10/02/03: pp. 82, 111). In some instances, when Orrego was running low in his inventory of the biopolymers, Orrego would call his son, an airline employee, who would transport the biopolymers from Miami to Puerto Rico through commercial airline flights. (T.T.: 9/30/03: pp. 28-29).

In addition to injecting clients at Evelyn Valentin’s salon, Orrego injected other clients in a beauty salon in Carolina, Puerto Rico that was owned and operated by Ms. María del Carmen Polanco. He paid approximately ten percent (10%) to fifteen percent (15 %) of the moneys charged to the customers to Ms. Polanco and kept the rest. Consistent with his conduct at Evelyn Valentin’s Salon, Orrego would not leave the substance used to inject customers at this salon. On days that he worked at the salon, he usually informed the owner that he was arriving directly to the salon from either the airport or his hotel. (T.T.: 10/7/03: 27, 28, 30, 38, 40, 44, 45, 49-50).

Whether the substance seized at the salon on March 20, 2002 was *Silicex* (a brand of liquid injectable silicone purchased by the defendant purchased from a business in Venezuela known as *Belleza Integral*) or biopolymer (another name for liquid injectable silicone) is irrelevant to defendant’s guilt as to the substantive counts of conviction and as to the conspiracy count. None of the substantive counts for which defendant was convicted of introducing liquid injectable silicone (Counts 3, 4, 5, 6, and 7) charge the importation of a particular brand of liquid injectable silicone. In addition, the vials containing liquid injectable silicone seized at Evelyn Valentin’s salon were found by the agents to lack labeling, thus, further impeding determining

the specific brand and manufacturer of the silicone.

Moreover, the matter under discussion does not constitute a “newly discovered evidence” claim, thus, defendant should have presented the same within seven (7) days of the guilty verdict. Defendant was represented at all times during the trial until verdict in the instant case by Assistant Federal Public Defender, Juan A. Matos, who was also his counsel when defendant was acquitted in another prior related case: United States v. Sergio López Gambino et al., Cr. No. 02-102 (JAG). Defendant had stand-by counsel Jorge A. Arroyo Alejandro, a former career AUSA who had afterwards been in private criminal practice in excess of ten years, assisting the defendant during post trial R. 29 motions and hearings.² In addition, the evidence fails to qualify as “newly discovered evidence” as any such evidence could have been reasonably discovered prior to and presented at trial. See also, United States v. Montilla Rivera, 115 F.3d 1064-1065 (requiring evidence that is “unknown or unavailable” at trial and not available “despite due diligence.”) (See No. 3 *infra*.)

III. Defendant argues as newly discovered evidence that the FDA internet site and testimony by FDA official Melvin S. Zymansky show that Kenacort A and Lignocaine BP 2% were approved by the USA. (Orrego’s Motion, Docket 207, pp. 5, 9-10).

Defendant was convicted in Counts Eight and Nine of introduction into interstate

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Defendant hence had Associate Public Defender Associate Matos for two full trials, Crim. 02-102 and the instant case (Cr. 02-465); counsel Jorge Arroyo Alejandro as stand-by counsel for Rule 29 post trial proceedings in the instant case and prior to counsel Arroyo, counsel Luis I. Santiago González. See Dockets 69, 70 and 84. The court initially denied the defendant’s *pro se* representation because of his apparent language barrier and because the court was convinced that his legal writings in English would have difficulty in being understood. Eventually, the court authorized counsel Jorge Arroyo as stand-by counsel for all post trial proceedings under R. 29. See Docket 69. The musical chairs, relating to three counsel in a relative short period of time, caused confusion to the court in wrongly thinking that defendant Orrego was duly represented and not in *pro se* fashion, as counsel Arroyo had a heightened participation as stand by counsel at the Rule 29 motion stage.

commerce of a non-approved new drug on March 18, 2002 from the Dominican Republic into the United States, in violation of Title 21, United States Code, Section 331(a) and 333(a)(2) and Title 18, United States Code, Section 2. Count Eight charges the introduction of two 50ml bottles of Lignocaine Injection BP 2%, while Count Nine charges the introduction of one 5ml bottle of Kenacort - A. The evidence to establish the importation by defendant into the United States of these substances is summarized in the table below:

COUNT	Substantive offense conduct	Evidence introduced at trial
EIGHT	Introduction of <i>Lignocaine Injection BP 2%</i> on or about March 18, 2002, from the Dominican Republic.	Orrego's passport (Govt. Exh. 3) shows him departing the Dominican Republic on March 18, 2002. Esthetics International evaluation sheets (Govt. Exh. 7) show that Orrego worked at Evelyn Valentín's salon on March 19, 2002. One bottle of <i>Lignocaine Injection BP 2%</i> (Govt. Exhibit 12), was seized at Evelyn Valentín's salon during the execution of a federal search warrant and arrest of Orrego at the salon on March 20, 2002.
NINE	Introduction of <i>Kenacort - A</i> on or about March 18, 2002, from the Dominican Republic.	Orrego's passport (Govt. Exh. 3) shows him departing the Dominican Republic on March 18, 2002. Esthetics International evaluation sheets (Govt. Exh. 7) show that Orrego worked at Evelyn Valentín's salon on March 19, 2002. One vial of <i>Kenacort - A</i> (Govt. Exhibit 23), was seized at Evelyn Valentín's salon during the execution of a federal search warrant and the arrest of Orrego at the salon on March 20, 2002.

Defendant claims as "new evidence" that both of these substances were approved by the FDA for use in the United States. Melvin S. Zymansky, of the FDA's Center for Drugs, testified that based upon information obtained from the labels of the products seized from Orrego of the Kenacort - A and the Lignocaine 2% injectable products, he conducted a search in the archives of the FDA's Center for Drugs and found that no such specifically seized products were approved

for use in the United States (T.T., October 2, 2003, p.32). Szymanski conducted the search as to these particular injected substances using three separate and independent methods: (a) based on the name of the drug, (b) based on the active ingredient and (c) based on the sponsor or manufacturer of the drug. He concluded that there existed no approval for the specific product of Kenacort - A in the form that it was provided to him, as far as the labeling of the product was concerned, based upon name, active ingredients, sponsor or manufacturer of the drug product.

The defendant claims that the active ingredient of Kenacort - A had been approved in the U.S. since 1958. Defendant makes no claim in his motion that the specific type of Kenacort - A product seized from him was approved by the FDA. If other forms or iterations of Kenacort - A have been approved by the FDA, is irrelevant. The determinant issue is whether the Kenacort - A seized from defendant was approved by the FDA or not.

Similarly, defendant claims that the Lignocaine 2% Injectable is similar to Xilocaine and Lidocaine 2%, products which defendant claims, were approved in the United States by the FDA. Even if that were correct, the defendant makes no claim in his motion that the Lignocaine 2% injectable product seized from him was approved by the FDA. Thus, defendant fails to claim that the two drugs object of Counts Eight and Nine were actually approved by the FDA. The fact that other similar branded products may have been approved by the FDA is irrelevant to this issue. The court notes that evidence of the existence of the FDA website was provided to defendant Orrego during the discovery phase of his first prosecution, Criminal No. 01-102, well before trial in this case.³

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The identity of FDA website was known to the defendant prior at trial because in the previous criminal case the United States notified evidence from the FDA website in the Government's Designation of Evidence in Cr.No. 02-102, see United States Motion in Compliance with the

In addition, since the claim on this aspect once again constitutes a question of law, the matter is not newly discovered evidence, the defendant is barred from presenting the same since the matter has been presented well beyond the seven (7) days of his guilty verdict. The court further determines, as to in “the interest of justice” argument made by defendant, that the argument falls short. The court briefly explains. The fact that other similar products may have been approved by FDA with similar names as Kenacort A, Xilocaine and Lidocaine 2% does not render the specific products of Kenacort A and Lidocaine injection BP 2% which were imported via international air carrier HDL have been previously approved by the FDA. **The specific drugs imported and used by Orrego were not approved by the FDA pursuant to the only evidence on the subject matter testified by witness Mr. Melvin S. Zymensky.** This was the only evidence presented at trial for the jury to consider and any other evidence, as argued by defendant Orrego, is irrelevant since other similar drugs, named similarly or having been already accepted, under different brands or allegedly having similarly chemical composition, does not mean that the specific drugs imported by Orrego via HDL (Dominican Republic and Venezuela) or imported from the Dominican Republic by Orrego himself (Counts Eight and Nine) were in fact in compliance with the other drugs previously accepted by the FDA.

IV. Orrego similarly argues, as newly discovered evidence, the existence of a photograph at the website of a Venezuelan business known as *Belleza Integral*, showing the

court’s November 6, 2007 order, (D. 230). Further, the identity of the Belleza Integral Website was also known to the defendant as defendant in the prior case notified documents from the Belleza Integral Website as reciprocal discovery, Cr. No. 02-102. Further, the United States notified to the defendant in the instant case in its discovery letter of March 20, 2003 the same evidence, that defendant Orrego previously notified as reciprocal discovery in Criminal No. 02-102. See Docket No. 230. Hence, the website of the FDA and of Belleza Integral were not “unknown or unavailable at trial” as required by United States v. Montilla Rivera, 115 F.3d at 1064-1065.

picture of a vial of Silicex and it reference therein as a “medical fluid.” (Orrego’s Mot., Docket 207, p. 9). Orrego fails to explain in his motion how this is exculpatory in any way. *Belleza Integral* shows in its website the picture of a vial of Silicex, which the defendant avers, is a brand of biopolymer, that is, liquid injectable silicone. Whether the vial shown in the *Belleza Integral* advertisement is identical to a vial shown in a photograph provided by the Government in discovery has no bearing on whether the product imported by the defendant was approved by the FDA. Thus, this is not an issue of newly discovered evidence. Further, the identity of the *Belleza Integral* website was available and accessible before trial.⁴ Since this issue is not one of newly discovered evidence, the defendant is barred from presenting the evidence since the matter has been presented well beyond seven (7) days of his guilty verdict. The court is not impressed as an argument under the reasoning of in “the interest of justice” for the same reasons expressed in Section III. (No connection proved between the pictured drug and the drug used by Orrego as a drug being previously approved by FDA.)

V. Orrego argues that the government witness, Sergio Lopez, presented hearsay statements to convict him. (Orrego Mot.: p. 9). The defendant avers a general argument without support from the record. Under the Federal Rules of Evidence, statements made by Orrego to Lopez were admitted in relation to products imported from Venezuela, Dominican Republic, or elsewhere by Orrego. Further statements made by Orrego to López as to a false document describing *Karthy Swed* as “shark cartilage” when in reality the product was petroleum jelly. (T.T.: 10/1/03: pp. 116, 134-135; 10/3/03: pp. 2-3, 11-12, 28, 30-31,37). These and other statements made by defendant Orrego to López were admissible as either (1) admissions testified

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See Note #3.

by co-defendant López of a party-opponent to the U.S. attributed to Orrego, under Rule 801(d)(2)(A), United States v. Payne, 437 F.3d 540, 547 (6th Cir) (out of court statement as party admission produced by an accomplice against the defendant), United States v. Ríos Ruiz, 579 F.2d 670, 676-677 (1st Cir. 1978) (explaining reasoning behind admittance of party opponent out of court statements “. . . Rule 801(d) represents an accommodation to the common sense view that statements of a principal actor should generally be received rather than excluded per se. Because of their value they are receivable whether or not the declarant is available or appears as a witness;” and/or also as (2) co-conspirator statements made as a member of the conspiracy, (co-defendant Orrego), during and in furtherance of the conspiracy, under Rule 810(d)(2)(E). Bourjaily v. United States, 483 U.S. 171, 178-179 (1987); United States v. Capelton, 350 F.3d 231, 241 (1st Cir. 2003); United States v. Petrozzello, 548 F.2d 20, 23 (1st Cir. 1977). Moreover, again the matter fails to constitute newly discovered evidence and is purely a matter of evidentiary law which is an erroneous interpretation of the defendant as a matter of law.

VI. Orrego argues in the new trial motion that Sergio Lopez presented exculpatory new testimony at the Rule 29 hearing after the trial. (Orrego’s Motion, Docket 207, pp. 13-18, 21-33).

Throughout his motion for new trial, Orrego misstates López’s testimony at the post-trial hearings. For instance, at page 16 of his motion for new trial, Orrego states that Sergio López also stated in his post-trial testimony that he never “saw Orrego defraud U.S. Customs,” furthermore, “he never heard that Orrego was questioned by U.S. Customs Agents.” Orrego states that López so stated at pages 24-25 of the March 28, 2005 hearing. The court has not been able to locate any such statement. The only statement about U.S. Customs by López in those two

pages is the following:

Q. You said you never passed through U.S. Customs with me, right.

A. Not together, correct.

This is not inconsistent with López's testimony at trial, where López stated that he learned from Orrego himself, that Orrego had encountered trouble coming through Customs with the substances, a party opponent admission under Rule 801(d)(2)(A). López testified, as follows, on October 3, 2003, page 3, Trial Transcript:

Q. Now, do you recall any incident that Mr. Orrego ever had at an airport?

A. On one occasion he told me that he had been questioned for bringing over the implants that he held in his handbag. So then at that conversation that we held, he remarked that he would asks the laboratories that send the product over to him to prepare an explanatory sheet indicating what those products were for, and for purposes of bringing through Customs it would be labeled for cosmetic purposes, samples.

In light of the above, the testimony of López is not exculpatory when examined in context with López's testimony as a whole. Further, as discussed *infra* the instant case fails to qualify as a good candidate for new trial considering the overwhelming evidence of guilt. (See discussion *infra*.)

In addition as stated above, it is immaterial whether or not Sergio López knew the specific drugs imported and used by Orrego. This part of the conspiracy was delegated to Orrego.

VII. OVERWHELMING EVIDENCE OF GUILT INDEPENDENT OF SERGIO LOPEZ

During the trial, the Government presented numerous witnesses, other than Sergio López,

and documents belonging or related to the defendant, that establish (1) that Orrego agreed with Sergio López to introduce adulterated devices with intent to defraud, and mislead and (2) that Orrego introduced into the United States adulterated devices and/or non-approved new drugs with intent to mislead. A summary of these witnesses follows:

Johanna Rosaly. Rosaly is a renown actress who was then injected with liquid injectable silicone for a facial line correction performed by Orrego in order to later promote the injections in a general circulation magazine in Puerto Rico. Rosaly testified that defendant was identified to her as a doctor (T.T., 9/25/03, p. 30). Further, everyone at the Evelyn Valentin's salon referred to him as "doctor" in front of Rosaly. (T.T., 9/25/03, p. 44) Said evidence constitutes circumstantial evidence of intent to mislead customers enabling them to believe that defendant was a physician consequently authorized to perform cosmetic services.

Carmen Pacheco. She was a client of the Evelyn Valentin's salon who was also injected liquid injectable silicone for facial line correction by the defendant (T.T., 10/01/03, p. 78). She testified that Sergio López told her that Orrego was a physician (T.T., 10/01/03, p. 79). This particular evidence constituted circumstantial evidence of an agreement between López and Orrego to mislead the customers into believing that Orrego was a doctor authorized to provide the facial treatment at the salon. Pacheco also testified that she referred to Orrego in his presence as "doctor," Orrego never corrected her statement. (T.T., 10/01/03, p. 80) She further testified that after being injected by the defendant she developed complications such as swelling and a serious infection. Ms. Pacheco then questioned Orrego repeatedly if he was in fact a doctor. Orrego stated to her that he was, further showing defendant's intent to mislead, even to the extent that Orrego's deceiving conduct caused serious health harm to a treated person. (T.T., 10/01/03,

p. 104).

Milagros Rivera. She was injected liquid injectable silicone for a facial line correction by the defendant at Evelyn Valentín's salon after the Orrego falsely informed her that the substance was approved by the FDA. The defendant further stated that he was a doctor, showing defendant's intent to mislead and knowledge that the substance he was injecting was prohibited in the United States. (T.T. 10/01/03, p. 6) She also asked Orrego if the substance was silicone. Orrego stated to her that it was not. (T.T. 10/10/03, p. 14)

Evelyn Valentín. Valentín allowed the defendant Orrego and Sergio López to partially operate her business specifically authorizing Orrego to use on her clients biopolymer injections at the beauty. The defendant Orrego deceived the clients faking to be a physician, obviously with the apparent capacity to provide the treatment. Said conduct showed intent to mislead (T.T. 09/30/03, p. 18). López had told her that the biopolymer was approved by the FDA (T.T. 09/30/03, p. 23) She was further injected liquid silicone for facial line correction by the defendant. (T.T., 09/30/03, p. 22). She testified that in one occasion Orrego was short of biopolymer inventory at the salon. Orrego called his son, who worked in an airline company; the son arrived later with additional biopolymer at the salon. (T.T. 09/30/03, p. 28)

Luisa Frener She was an esthetician working at Evelyn Valentín's salon. She testified that she assisted Orrego when he injected persons at the salon (T.T. 10/07/03, p.80). Frener testified that she believed that Orrego was a physician (T.T. 10/07/03, p.80) Clients injected by Orrego referred to him as "doctor." Frener addressed him as a doctor in front of other people; Orrego never corrected her that he was not a doctor. (T.T. 10/07/03, p.81) Frener never saw Orrego clarifying to the clients that he was not a physician (T.T. 10/07/03, p.83). The above

described evidence constituted circumstantial evidence as to defrauding the clientele that Orrego being a physician having the knowledge to provide drug beauty treatment. Frener stated that the product denominated *Karthy Swed* was one of the substances used by Orrego to inject the clients. (T.T. 10/07/03, p.89).

María del Carmen Polanco She was the owner of a beauty salon in Carolina, Puerto Rico, where the defendant also injected clients with biopolymer (liquid injectable silicone). She testified that she dealt only with Orrego, and that she did not know any person by the name of Sergio López. (T.T. 10/07/03, p.29-30). The salon of María del Carmen Polanco received 15% of the profit from the biopolymer injections, while Orrego received 85% of the net amount produced from the clients at the salon. (T.T. 10/07/03, p.30) The Government introduced into evidence Polanco's agenda (Government's Exhibit 59), which listed clients of her salon who had appointments with Orrego for evaluation or treatment. (T.T. 10/07/03, p.32) The agenda reflected that Orrego injected client's at Polanco's salon on January 18, February 19 and March 18, 2002. The Government also introduced into evidence Exhibits 64 and 65, constituting evaluation sheets of clients. In those documents, Orrego would specify the areas of the body to be injected with biopolymer and the billing amount to the client. (T.T. 10/07/03, p.43-45). Government's Exhibit 61 was an invoice that María del Carmen Polanco prepared for Orrego. The document showed the amounts paid by Polanco to Orrego on March 18, 2002. (T.T. 10/07/03, p.46-47) Polanco further testified that after Orrego finished working on a particular date in her salon, he would take with him the substances. She further stated that whenever Orrego arrived at her salon she inquired where he had come from; Orrego informed her that he came from the hotel or the airport. Further, when arriving from the airport, he stated that he had

arrived from Santo Domingo (Dominican Republic) or Miami (showing interstate and/or international commerce movement of the illegal not authorized drugs). Maria del Carmen Polanco was shown Government's Exhibit 8-A, Orrego's monthly planner, specifically the page for March 2002, which showed an entry for March 18 that read: "María del Carmen" and the number "2,060" beside it, which was identified by Ms. Polanco as the amount of money paid by "María del Carmen" Polanco to Orrego on said date. (T.T. 10/07/03, p.49-51)

Nelson Cardona He was a bank officer for Banco Popular who testified that on July 21, 2001 Orrego opened a bank account at the Banco Popular branch where Cardona was working. Cardona stated that he personally interviewed Orrego and that, as part of the bank account opening process, Cardona asked Orrego as to his occupation. Orrego stated that he was a physician. Cardona registered Orrego's answer in Orrego's bank opening documents (Government's Exhibit 72). (T.T. 10/14/03, p.5)

Carlos Orrego During defendant's testimony, it was established that Orrego had no license to practice medicine anywhere in the world (T.T. 10/15/03, p.53-54). Orrego also admitted that he did not have an investigational device exemption by the FDA and that he did not have a pre-market approval by the FDA for any substance (T.T. 10/15/03, p.54); that he injected about two hundred individuals in Puerto Rico, mostly at Evelyn Valentín's beauty salon (T.T. 10/15/03, p.85); that Evelyn Valentín asked him about his medical license (T.T. 10/15/03, p.89); that he had knowledge the substance he was injecting was silicone (T.T. 10/15/03, p.93). Orrego further testified that he had an arrangement with Sergio López, where he was paid 50% of the profits. Orrego was the person responsible for purchasing and transporting the biopolymer. (T.T. 10/15/03, p.127-128). Orrego also stated that he owned a medical center in South Miami. (T.T.

10/14/03, p.72)

Documents In addition to the witnesses other than Sergio López, the government also presented into evidence Orrego's passport (Government's Exhibit 3) and the passport of Sergio López (Government's Exhibit 2); an examination of entries of both passports revealed at least five (5) dates in common when both departed from the Dominican Republic traveling to the United States (Puerto Rico):

Dates where Orrego's and López's passports have identical departure dates from the Dominican Republic	Documentary evidence that Orrego traveled to Puerto Rico to inject biopolymers (liquid injectable silicone)
November 20, 2001	Orrego's Agenda's (Gov't Exh. 8-A) shows that he worked at María del Carmen Polanco's salon that day.
November 29, 2001	Exhibit 38 (Esthetics Int., Daily Report: Nov. 2001) shows Orrego worked that day at Evelyn Valentín's salon.
December 18, 2001	Exhibit 39 (Esthetics Int. Daily Report: Dec. 2001) shows Orrego worked the next day at Evelyn Valentín's salon.
January 18, 2002	Gov't Exhibit 59 (Client listing at Polanco's salon) shows that Orrego worked on that date in Polanco's salon. The next day (January 19), Orrego worked at Evelyn Valentín's salon, as per Exhibit 40 (Esthetics Int. Daily Report: Jan. 2002)
March 8, 2002	Orrego's agenda (Gov't Exh. 8-A) shows that Orrego worked at Evelyn Valentín's salon on this date.

The record reflects that, apart from Sergio López, other witnesses, documents, and seized products, established conclusively and beyond any reasonable doubt that the defendant introduced into the United States adulterated devices (liquid injectable silicone and *Karthy Swed*) and non-approved new drugs (*Kenacort - A* and *Lignocaine 2%*) with intent to mislead customers of at least one beauty salon. Thus, the evidence presented at trial, apart from López's testimony, was overwhelming as to Orrego's guilt for the offenses for which he was convicted.

Orrego has failed to show that López's post-trial testimony exculpates him in relation to

the agreement between López and Orrego, through which agreement Orrego's responsibilities included importing into the United States the substances, that is, liquid injectable silicone, *Karthy Swed* and drugs used in connection with the treatments. Orrego attempts through López's post-trial testimony, to establish that he (Orrego) had no knowledge of the unlawfulness of the substances he was using. In this case, the evidence presented by the Government, independent of López's testimony, was overwhelming, as shown above. See e.g. Ruiz v. United States, 339 F.3d 39, 43 (1st Cir.2003) (new trial not warranted in arson case upon discovery of report indicating prior gas leak because cumulative weight of evidence was overwhelming.) See also, U.S. v. Singh, 54 F.3d 1182, 1190 (4th Cir.1995) (new trial not warranted by newly discovered evidence that witness had been intimidated into acting as informant because other evidence overwhelmingly supported conviction.)

VIII. Orrego argues as newly discovered evidence that Jose Coca's testimony would have been different had he been shown the *Belleza Integral* website showing Silicex. (Orrego's Mot., Docket 207, pp. 18-20).

This argument is meritless. First, the *Belleza Integral* website is not newly discovered evidence since the existence of that website was well known to the defendant Orrego before trial, as in the prior trial, counsel for Orrego submitted as reciprocal evidence, Belleza Integral documents from that website. (See Fn. #3). Furthermore, Jose Coca worked for DHL and, apart from the shipping labels and invoices, did not know what was contained within the shipped box addressed to Orrego. His testimony was limited to the description on the package label. Showing the website page would not have assisted the defendant in any form at trial. Even if Orrego could have established at trial that he did not inject Silicex into any person in Puerto

Rico, the fact remains that Orrego caused its importation from Venezuela into the United States, and there was no evidence in the trial that Orrego used Silicex or any other brand of liquid injectable silicone for anything else than injecting it into human beings for cosmetic purposes.

RECAPITULATING

The standard to grant a motion for new trial is “if the interest of justice so requires.” Most of the requests set forth in defendant motion are not allegations of newly discovered evidence, since the evidence was available prior and during trial; others are matters purely constituting an issue of law which is erroneous in the court’s opinion. In relation to the allegations of new exculpatory testimony by Sergio López, there was overwhelming evidence of guilty against the defendant from testimonial and documentary evidence independent of Sergio López’s testimony, to establish that defendant agreed with López to conspire to unlawfully introduce adulterated devices and non-approved new drugs. Further, the evidence supports the conviction of the defendant as to the substantive offenses of introduction of adulterated devices and non-approved drugs found in counts 3 through 9. The evidence as a matter of law was overwhelming against the defendant, the verdict was not “against the great weight of the evidence,” United States v. Arena, 918 F. Supp. 566; likely to result in an “acquittal upon retrial.” United States v. Montilla Rivera, 115 F.3d at 1064-1065; nor does this case present a case of a “miscarriage of justice” or that the evidence “preponderates heavily against the verdict.” United States v. Leach, 427 F.2d at 1111.

Therefore, the defendant's motion for new trial is **DENIED**.

IT IS SO ORDERED.

In San Juan, Puerto Rico, this 11th day of December, 2007.

S/ Daniel R. Domínguez
DANIEL R. DOMINGUEZ
U.S. DISTRICT JUDGE